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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/079,758	05/15/98	MORRISON	D MSC-22939-1-

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EXAMINER

SHARAREH, S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED:

06/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/079,758

Applicant(s)

Morrison et al

Examiner
Shahnam Sharareh

Group Art Unit
1616



☒ Responsive to communication(s) filed on Mar 22, 1900

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-71 is/are pending in the applicat

Of the above, claim(s) 60-68 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-59 and 69-71 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

The amendment filed on March 22, 2000 has been entered. Accordingly, claims 2-4 have been amended. Claims 1-59, and 69-71 are pending in this application. Claims 60-68 stand withdrawn.

Response to Arguments

Claim Rejections - 35 USC § 112

1. The amended claims 2-4 overcome the rejections made under 35 USC § 112. Said rejection is withdrawn.

Priority

2. Applicant's request for priority is acknowledged. The instant Application is recognized as a continuation-in-part of US Application No. 08/349,169 filed December 2, 1994, now US Patent 5,827,531.

Claim Rejections - 35 USC § 102

3. Applicant's arguments with regard to the rejection made under 35 U.S.C. 102(e) as being anticipated by Unger et al US Patent 5,852,752 have been fully considered but are not persuasive. Specifically, Applicant has not presented evidence to show an unobvious difference between the cited art and the instant claims.

Applicant argument is on the basis that Unger et al do not teach encapsulation of an energy absorbing component that when heated to a temperature beyond the melting point of the outer membrane by the absorption of energy. In response Examiner states that the independent claim 1 recites a limitation for the function of an energy absorbing component which does not

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cause a structural difference between the claimed invention and the prior art. The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977) The independent claims of the instant application are drawn to microcapsules comprising one or more internal containing immiscible liquid phases, an outer polymer membrane, one or more energy absorbing components in an internal liquid phase; a magnetic particle, a drug or drug precursor. More specifically the material used to form multi-lamellar microcapsules comprising lecithin (phospholipids), polyvinyl pyrrolidone (PVP), and polyvinyl alcohol (see instant specification page 40, and example IV.) Unger disclose a liposome comprising lecithin, polyvinyl pyrrolidone, and polyvinyl alcohol (see claims 1, 10, 17, 21, 22.) for controlled drug delivery of pharmaceutically active agents utilizing an energy source (see col 25 lines 17-22, col 40 lines 20-29.) Unger's composition further comprising one or more internals (see col 21 lines 18-20); an outer polymer membrane (see col 20 line 46-67, col 21 & 22); an emulsifying agent such as TWEEN or sorbitan monooleate; an suspending agent such as glycerol, alginate, aluminum monostearate, aluminum silicate (see col 23 lines 39-66 and col 25 lines 59-67); a paramagnetic particle (see col 33 lines 46-55); various drug or drug precursors selected from therapeutic classes such as antibiotics, anti cancer, antiinflammatory, antifungal (col 32 lines 37-60, col 33 lines 46-67, col 34-35), in variety of sizes (see col 27 lines 11-41) delivered to specific sites via a pharmaceutically acceptable solution (see col 26 lines 3-30). Unger et al also disclose methods of delivering said microcapsule comprising administering the drug delivery solution to a subject and exposing the microcapsule to an energy source (see col 27 lines 56-65, col 40 lines

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20-30). Once a reference teaches a product that appear to be identical so that the Examiner presents reasoning tending to show inherency, the burden shifts to the Applicant to show an unobvious difference.

The policy of the US PTO is to give pending claims their broadest reasonable interpretation. The instant open-ended claims comprise and do not exclude any components essential to the operability of the cited prior art patents. Thus, claims 1-59, 69-71 stand rejected.

Applicant's arguments filed in respect to the rejection made under 35 U.S.C. 102(b) as being anticipated by Grinstaff et al US Patent 5,498,421 have been fully considered and are not found persuasive.

As stated in the previous Office Action Grinstaff et al disclose a polymeric shell for delivery of biologicals comprising an outer polymer membrane that can be attached to components such as metal particles selected from the group consisting of iron, iron oxide, and manganese, which inherently possess energy absorbing properties; a biocompatible dispersing agent such as soybean oil, corn oil, cotton seed oil, a drug selected from various therapeutic classes, in a pharmaceutically acceptable carrier (see abstract, col 7 lines 10-14, col 8 lines 1-55, col 14 lines 26-36, col 25 lines 1-21, example 47.) The mere recitation of "energy absorbing component" in the instant claims does not exclude all the components that are described in the prior art which possess this property. Grinstaff et al disclose all the components described in the instant claims, therefore, their composition possess similar characteristics regardless of the functionality of the individual component within their polymeric entity. Thus, claims 1-43, 69-71 stand rejected.

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Applicant's arguments in respect to the rejection made under 35 U.S.C. 102(b) as being anticipated by McGinity et al US Patent 5,288,502 have been fully considered and are not found persuasive.

As described in Paper No.7 McGinity's microspheres comprise two liquid immiscible phase comprising Tween 80. The instant specification recognizes Tweens as an energy absorbing material, thus Tween 80 possess energy absorbing qualities. Accordingly, the microspheres of McGinity have the same characteristics as the instant microcapsules.

The policy of the US PTO is to give pending claims their broadest reasonable interpretation. The instant open-ended claims comprise and do not exclude any components essential to the operability of the cited prior art patents. Applicant is suggested to draw a clear mark of demarcation between the cited prior art and the claimed invention. Claims 1, 3-9, 11, 21-23, 31-35, 40-43 stand rejected.

Applicant's arguments in respect to the rejection made under 35 U.S.C. 102(b) as being anticipated by Tsuei et al US Patent 5,589,194 have been fully considered and are not found persuasive. rejected under 35 U.S.C. 102(b) as being anticipated by Tsuei et al US Patent 5,589,194.

As described in previous Office Action, Tsuei et al disclose the use of all components essential in the instant claims. The different functionality of individual component does not impart patentability, because the invention as a whole comprise the same characteristics as do Tsuei's composition. Claims 1-4, 6-8, 21, 24, 26-27, 36, 40-44, 69-71 stand rejected.

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Claim Rejections - 35 USC § 103

4. Applicant's arguments in respect to the rejection made under 35 U.S.C. 103(a) as being unpatentable over Tsuei et al US Patent 5,589,194, and Unger et al US Patent 5,853,752 have been fully considered and are not found persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the knowledge generally available to one of ordinary skill in the art. Furthermore, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Both cited prior art teach the use of energy absorbing material and external energy in activation of their respective compositions. In addition, the instant claims comprise and do not exclude any components essential to the operability of the cited prior art patents. Therefore, the combined teachings of the cited prior art renders the instant invention obvious. Claims 1-59, and 69-71 stand rejected.

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New Matter

Applicant's arguments in respect to the rejection made under 35 U.S.C. 112 first paragraph as containing new matter have been fully considered and are found persuasive. Said rejection is withdrawn.

Conclusion

3. No claims were allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 9:00 a.m. to 5:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Diana Dudash can be reached on 703-308-4628. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or

Application/Control Number: 09079758

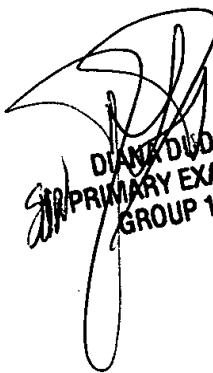
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proceeding should be directed to the Group receptionist whose telephone number is 703-308-

1235.

sjs, 6/07/00


DIANE D. DASH
PRIMARY EXAMINER
GROUP 1100